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Filed : February 29, 2000

## REMARKS

Claim 13 has been canceled. Claims 10 and 11 have been amended to clarify the invention. Support for the amendments can be found in Examples 1-3 on pages 8-10, and on page 5, for example. No new matter has been presented. Applicant respectfully requests entry of the amendments and reconsideration of the application in view of the amendments and of the following remarks.

### Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 2-8 and 10-15 have been rejected under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement. The Examiner notes that “[t]he claims are directed to a process requiring nuclease or alkali hydrolysis to obtain polyamines under certain process conditions and in some claims in an amount 2-3.2 times the amount of polyamines obtained in the absence of this hydrolysis step at certain process conditions.” The Examiner asserts, however, that “there is no indication regarding the location of support for this material. Clear basis or support is not found for the material now claimed.”

However, the specific claim limitations set forth in the pending claims are fully supported by the originally-filed specification. For example, “extracts obtained from yeast by physical crushing, extracts obtained from yeast by autolysis, extracts obtained from yeast with hot water, and yeast RNA compositions” is supported at pages 3-4. The limitations found in Claim 10 that “yeast somatic components are treated in solution with nuclease added in a concentration of approximately 1-2 mg/ml, at approximately 25-37°C, and at a pH of approximately 6-8” are supported by, *inter alia*, Example 1, at pages 8-9. Furthermore, the limitation of Claim 10 that “yeast somatic components are dissolved in a 0.3 N alkali solution at 37°C” is supported by Example 2, at page 9. Analogous limitations of other pending claims are likewise supported.

With respect to the disclosure of yield ranges, the Examiner has previously recognized that the specification provides “exemplification of a yield of polyamines up to 3.2.” Office Action mailed May 21, 2002 (Paper No. 11), at 2.

Furthermore, the Applicant respectfully disagrees with the Examiner’s assertion that the pending claims are overbroad in view of, *inter alia*, Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 45 U.S.P.Q.2d 1498 (Fed. Cir. 1998). It is well settled that “[i]n order to satisfy the

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written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.” Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323, 56 U.S.P.Q.2d 1481, 1483 (Fed. Cir. 2000). M.P.E.P. 2163 states “If the originally filed disclosure does not provide support for each limitation, or if an element which applicant described as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. § 112, paragraph 1, as lacking adequate written description.” Here, as discussed above, the originally filed disclosure legally and factually provides support for each limitation. Thus, the Examiner appears to assert “an element which applicant described as essential or critical is not claimed.” This is well in consistent with the Examiner’s assertion described in the Office Action mailed July 22, 2003 (Paper No. 19), at 3. In the Action, the Examiner asserts “It appears that a clause is omitted in this sentence, such as an indication of the time period of digestion or hydrolysis.” “The time period” used in Examples 1-3 of the present specification was 15-18 hours. However, a time period of 15-18 hours is not essential or critical and should not be required to be recited in the claims.

As shown by the appended Tanimoto Declaration, the yield obtained after one hour is nearly as high as that achieved after 15-18 hours (¶¶7, 8). A significant increase in yield is observed after 0.1 hours (¶¶7, 8). Clearly, a time period of 15-18 hours is not essential or critical, and as described in the application as filed, a time period of 0.1-24 hours (page 5, lines 8 and 19) is effective.

Gentry Gallery simply stands for the proposition that “a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope.” Cooper Cameron Corp. v. Kvaerner Oilfield Prod. Inc., 291 F.3d 1317, 1323, 62 U.S.P.Q.2d 1846, 1851 (Fed. Cir. 2002). In Gentry Gallery, the court’s holding that the claims were invalid as overbroad was “premised on clear statements in the written description that described the location of a claim element--the ‘control means’--as ‘the only possible location’ and that variations were ‘outside the stated purpose of the invention.’” Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 993, 50 U.S.P.Q.2d 1607, 1613 (Fed. Cir. 1999). Applicant respectfully submits that such “clear statements” of limitation are not present in the originally-filed specification. To the contrary, at page 5, the specification clearly discloses treatment of yeast somatic components by nuclease digestion or alkali hydrolysis for a period within a range

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of 0.1-24 hours. Nothing in the specific Examples disclosed would indicate to one skilled in the art that, for example, a narrower reaction time range was “an important defining quality” of the claimed invention. See Purdue Pharma, 230 F.3d 1320, 1327, 56 U.S.P.Q.2d 1481, 1486. The appended Tanimoto Declaration also states that “The yeast somatic components were subjected to the decomposition step for 15-18 hours as described in Examples 1-3 of the present specification. This was because we simply left the reaction materials overnight for convenience as is common practice for enzyme-related reactions. This was not because we thought that a time period of 15-18 hours was essential. If we set and left the experiments at 5 p.m. and came back at 9 a.m. the next day for evaluation, it would be 16 hours. We never state in the specification as originally filed that a time period of 15-18 hours was essential. On the contrary, we specifically state in the specification as originally filed that the reaction can be accomplished in 0.1 to 24 hours on page 5, lines 8 and 19.” (¶2). Applicant respectfully suggests that no further limitations, with respect to the reaction time range or otherwise, are required to render the present claims patentable. Applicant respectfully requests withdrawal of this rejection.

Claim Rejections – 35 U.S.C. § 112, second paragraph

Claim 10 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. As amended, Claim 10 recites “subjecting said yeast somatic components to a decomposition step, comprising nuclease digestion or alkali hydrolysis, of increasing the yield . . .” Applicant submits that the “step of [do]ing” language is approved for use in claims. See, e.g., Seal-Flex, Inc. v. Athletic Track and Court Construction, 172 F.3d 836, 850, 50 U.S.P.Q.2d 1225, 1234 (Fed. Cir. 1999) (Rader, J., concurring) (discussing interpretation of “the phrase ‘steps of’” in patent claims); Manual of Patent Examining Procedure § 2181. Applicant respectfully submits that the claim as amended is not indefinite and requests withdrawal of this rejection.

Claim 13 has been rejected under 35 U.S.C. § 112, second paragraph. Claim 13 has been canceled without prejudice. This rejection is no longer applicable.

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### **CONCLUSION**

In light of the Applicant's amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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